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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/893,005

06/28/2001

Hakuo Ikegami

IKEGAMI=2

6398

7590

11/02/2004

BROWDY AND NEIMARK, P.L.L.C.
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EXAMINER

HELMER, GEORGIA L

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/893,005

Applicant(s)

IKEGAMI ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16, 18-21 and 32 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16, 18, 19 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 20 and 21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 June 2004 has been entered.

Status of the Claims

2. Claims 11-16, 18, 20 and 21 have been amended. Claims 11-16, 18-21 and 32 are pending. Claims 20 and 21 are nonelected, as discussed below. Claims 11-16, 18-19 and 32 are examined in the instant action.

3. All rejections not addressed below have been withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

5. Newly submitted claims 20 and 21 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Invention I (claims 11-16, 18-19 and 32) is drawn to transgenic plants, class 800, subclass 295, for example, and invention II (claims 20 and 21) drawn to a food composition, class 426, subclass 615, for example.

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Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have operation, different functions, or different effects. The transgenic plants of group I are pharmacological agents and function as pharmacologicals. The Food comprising of Group II are nutritional resources for humans and other animals which are used for energy production by them; they are comprised of different materials (edible material). Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Group I claims (11-16, 18-19 and 32) are examined in the instant action and Group II claims (20 and 21) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112 second

6. Claims 11-16, 18-19 and 32 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

In claim 11,

- line 1, "grown-up" is indefinite and ambiguous. A "grown-up" plant can be a plant at any stage from germinating seed to seed-set and senescence.

Is this a flowering plant? Or a plant having seed?

Applicant's arguments filed 18 June 2004 have been fully considered but they are not persuasive. The term "grown-up" is rejected as indefinite and ambiguous (Office Action of 1 July 2003). Applicant traverses (Response, p. 5) "it is clear from the definitions in the dictionary (pages included in response) that 'grown-up' means adult and that adult means an animal or plant that is fully developed"; Applicant cites p. 20 and 32 of the specification, saying that the word usage context clearly means fully developed plants. This is unpersuasive. Applicant's cited dictionary term (p. 619), "grow", has several definitions, one of which is "to increase in size and develop towards maturity, as a plant ..does by assimilating food". Clearly, since alternate definitions exist, as evidenced by Applicant's cited definition, the term "grown up" is ambiguous. It is suggested that "grown-up" be deleted.

Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 112

7. Claims 11-16, 18-19 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The phrase "grown-up" is not supported by the originally filed specification or claims.

Applicant traversed (Response, April 2003) citing p. 20 and 23 (1st full ¶ of each) of the specification. Applicant's arguments have been fully considered but they are not persuasive. The term in question, "grown-up", does not appear in Applicant's cited support in the specification.

Claim Rejections - 35 USC § 102

8. Claims 11-16, 18 and 32 are rejected under 35 USC 102 (b) as being anticipated by Goodman, et al (US #4, 956, 282, issued September 11, 1990), for reasons of record, which are repeated in part below. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Goodman teaches

- A transgenic plant produced from an edible plant (column 4, lines 57-60),
- transforming the plant with a DNA encoding a cytokine (column 3, line 20-30),
- of a mammalian origin (column 3, lines 11-30, and column 7, lines 27-33).

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- mammalian cytokines (column 3, line 20-30),
- mammalian interferon, (column 3, line 20-30),
- where the origin of the protein is murine (column 7, lines 27-33),
- where the plant is Solanaceous (column 4, lines 55-63),
- where the plant is in the form of tissue isolated from the whole plant body (column 4, lines 55-63, column 5, lines 51-59)),
- where the plant is in a processed form obtainable by extracting (column 5, lines 46-50).

Applicant traverses saying primarily that the disclosure of Goodman (column 5, lines 40-60) the cited paragraph as expressed with the words “may be”. That this means that the statements in the paragraph were made based on Goodman’s hope or speculation and did not really on experimental results (Response, page 8). Applicant further traverses that Goodman’s experimental results do not refer to “grown-up” plants, rather the results stop at the stage where callus is obtained.

Applicant's traversal is unpersuasive.

Goodman teaches transgenic tobacco plants (column 8, lines 50-63, especially lines 60-63).

Applicant further asserts that Goodman et. al. do not teach an DNA having constitutive, inducible or tissue specific regulatory sequences (Response, 17 June 2004, p. 10).

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Applicant's traversal is unpersuasive. Goodman teaches constitutive, inducible or tissue specific regulatory sequences (column 2, lines 43-58).

Applicant further traverses (that Goodman et. al. does not teach "a cytokine in an amount of 0.1 ng to one milligram per one kilogram by fresh weight of the grown up transgenic plant'.

Applicant's traversal is unpersuasive. Applicant's claims (claim 11, lines 11-13) and all claims dependent thereon, are drawn to a transgenic plant comprising "a cytokine in an amount of 0.1 ng to one milligram per one kilogram by fresh weight of the grown up transgenic plant". Applicant's method steps are identical to those of Goodman, as discussed above. Applicant's starting materials are identical to Goodman's. Therefore, the percentage yield would have been an inherent property of the DNA construct used. If Applicant's percentage yields are different from that of Goodman, then the element(s) or step(s) resulting in such difference must be set forth in the claims to distinguish Applicant's invention to the prior art.

Accordingly Goodman anticipates the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. Claims 11-16, 18-19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman, as discussed above for claims 11-16, 18 and 32, in view of Vogel et al, J Exper. Botany. 52, 1817-1826, 2001.

The teachings of Goodman are discussed above. Goodman does not teach further supplementation with trehalose. The addition of sugars to food is notoriously well known. The supplementation of food with trehalose, a sugar, is a design choice well within the means of one of ordinary skill without any surprising or unexpected results. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

Applicant traverses saying primarily (Response, p. 11) that Vogel et. al. do not disclose a "grown-up" plant. Applicant's traversal is unpersuasive. Vogel et. al. is used in a § 103 rejection, which does not require anticipation as Applicant suggests it would. Quoting from above:

*A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, **if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.***

Accordingly, the claimed invention remains prima facie obvious in view of the prior art.

REMARKS

11. No claims are allowed.

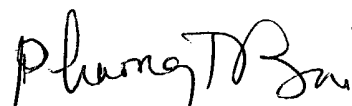
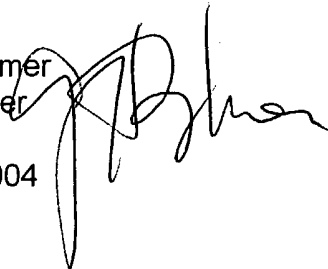
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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
October 28, 2004



PHUONG T. BUI
PRIMARY EXAMINER

10/28/04